

EPA Reg. No. 2596-178
Vol. 2



March 15, 2016

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 is submitting this notice under provision of our Conditional Registration to supply a projected "release for shipment date" for the following products:

- Hartz Reference 143, EPA Reg. No. 2596-178 and;
- Hartz Reference 144, EPA Reg. No. 2596-179.

The shipment dates for both are projected for March 18, 2016.

If you have any additional questions or need any information, please feel free to contact me at 201-271-4800, ext. 7562 or email me at lhemsarth@hartz.com.

Sincerely,

A handwritten signature in black ink that reads "Lance Hemsarth". Below the signature, the date "3.15.16" is written inside a hand-drawn oval.

Lance Hemsarth
Senior Director, Research and Development

PROCESSING REQUEST

Reg # 2596 - 178

Decision # 513130

Description: Minor revisions & additional claim

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☒ Dated: 2-6-16

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Angela Hollis

Division: RD

Phone: 347-0216

Date: 2-9-16



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 6, 2016

W. Lance H. Hemsarh
Senior Director R&D
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Subject: Notification per PRN 98-10 – Minor Revisions and additional claim
Product Name: Hartz Reference #143
EPA Registration Number: 2596-178
Application Date: 1/12/2016
Decision Number: 513130

Dear Mr. Hemsarh:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed within a large, hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

January 12, 2016

Hartz® Reference # 143

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

Hartz® Pro Force™ for Dogs (&) (and Puppies)
Hartz® FieldForce Pro™ for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ for Dogs (&) (and Puppies)

Hartz® Pro Force™ Triple Action Topical Solution for Dogs (&) (and Puppies)
Hartz® FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

FieldForce Pro™ for Dogs (&) (and Puppies)
First Defense Pro™ for Dogs (&) (and Puppies)
FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

NOTIFICATION

2596-178

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

02/06/2016

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
Pyriproxyfen.....	0.25%
OTHER INGREDIENTS	81.15%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS:

January 12, 2016

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 - 22 lbs.	0.023 fl. oz. (0.67 ml.)(Applicator)
23 - 44 lbs.	0.045 fl. oz. (1.34 ml.)(Applicator)
45 - 88 lbs.	0.091 fl. oz. (2.68 ml.)(Applicator)
89 - 132 lbs.	0.136 fl. oz. (4.02 ml.)(Applicator)

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 - 22 lbs.	0.069 fl. oz. (2.01 ml.), Contains 3(-) (tubes, each) 0.023 fl. oz. (0.67 ml.)(Applicators)
23 - 44 lbs.	0.135 fl. oz. (4.02 ml.), Contains 3 (-) (tubes, each) 0.045 fl. oz. (1.34 ml.)(Applicators)
45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3(-) (tubes, each) 0.091 fl. oz. (2.68 ml.)(Applicators)
89 - 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 (-) (tubes, each) 0.136 fl. oz. (4.02 ml.)(Applicators)

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 - 22 lbs.	0.138 fl. oz. (4.02 ml.), Contains 6 (-) (tubes, each) 0.023 fl. oz. (0.67 ml.)(Applicators)
23 - 44 lbs.	0.27 fl. oz. (8.04 ml.), Contains 6 (-) (tubes, each) 0.045 fl. oz. (1.34 ml.)(Applicators)
45 - 88 lbs.	0.546 fl. oz. (16.08 ml.), Contains 6 (-) (tubes, each) 0.091 fl. oz. (2.68 ml.)(Applicators)
89 - 132 lbs.	0.816 fl. oz. (24.12 ml.), Contains 6 (-) (tubes, each) 0.136 fl. oz. (4.02 ml.)(Applicators)

January 12, 2016



(1.5 x 1.5 cm icon)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panel. The icon will appear in a black lined yellow box.]

DO NOT USE ON CATS

BACK PANEL

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS. CAUTION.**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty four (24) hours per day, seven (7) days per week.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

January 12, 2016

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

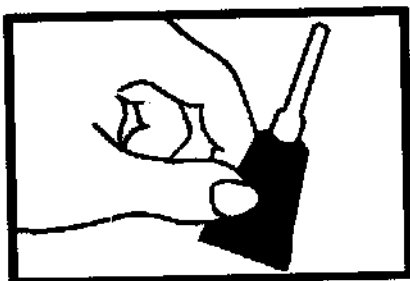
READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER
DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS
DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT
DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS
THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER

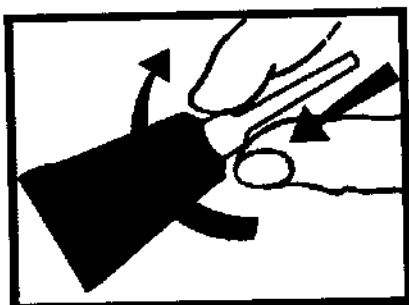


(Place in a 1.5 x 1.5 cm yellow box with black images only.)

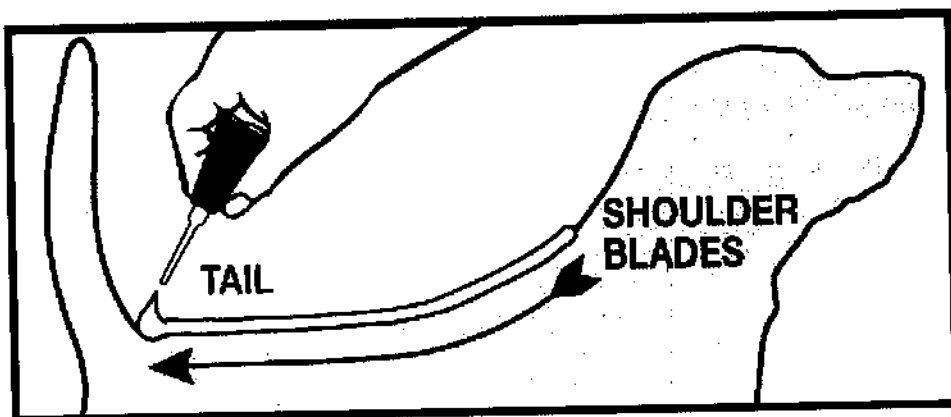
DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to or ingested by a cat, contact your veterinarian.



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



3 Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

4 Repeat every month.

January 12, 2016

SIDE EFFECTS

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to three months. PRODUCT NAME also prevents development of all flea stages for up to three months. PRODUCT NAME kills ticks for at least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to three months, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

(With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.)

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal. Do not use or store near heat or open flame.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-178
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

January 12, 2016

[Product name]

For use ONLY on DOGS AND PUPPIES 8 WEEKS OR OLDER weighing *(insert from weight range list below)* -

5 - 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 - 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains Fipronil (9.80%), (S)-Methoprene (8.80%), Pyriproxyfen (0.25%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions

EPA Reg. No. 2596-178

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

[Adult Fleas]

Kills Fleas (for (28 days) (30 days) (1 month) (4 weeks))

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills newly emerged adult fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Starts killing fleas within 30 minutes* (mins)

*48 hours after initial application

[Both statements must appear on the same panel. The qualifying statement is to be in close proximity with the same font, color and background with font size being 40% or greater.]

January 12, 2016

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)
Prevents Flea Eggs from hatching
Kills flea eggs on your (dog *or* puppy *or* dog and puppy) that live in your home
Kills flea eggs on your (dog *or* puppy *or* dog and puppy) to prevent the eggs from hatching in your home.

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older
Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older
Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older
Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)
Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all biting stages of ticks
Kills adult (brown dog) (deer) ticks, nymphs and larvae
Kills Ticks including those that may transmit Lyme disease
Kills fleas, (kills) flea eggs, (kills) flea larvae and (kills) ticks (including those that may transmit Lyme disease)

[Lice & Mange]

Rapidly eliminates chewing lice infestations
Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, (Kills) Ticks, (Kills) Flea eggs, ((Kills) Flea larvae), (Kills) Chewing Lice
Kills Fleas, Ticks, Flea eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, and Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, and Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks and chewing lice (for dogs and puppies 8 weeks or older)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults in the home (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation
Prevents and controls re-infestation(s)
Dual insect growth regulator (IGR) prevents re-infestation
Contains two ingredients to prevent flea infestations

Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
Waterproof
Effective after bathing
Effective after exposure to water
Easy spot on topical applicator
Patents Pending

Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Convenient to use
Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.
(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)
(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)
Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- **Fast Acting**
- **Long Lasting**
- **Waterproof**

Only for dogs and puppies 8 weeks of age or older
Specially formulated for dogs and puppies 8 weeks of age or older

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose, 4th dose, 5th dose, 6th dose

First month, second month, third month, fourth month, fifth month, sixth month

Value pack

1 month supply

3 month supply

6 month supply
1 (monthly) treatment
3 (monthly) treatment(s)
6 (monthly) treatment(s)
1 (monthly) dose
3 (monthly) doses
6 (monthly) doses
Apply (monthly) (every 30 days)
Convenient (easy to use) applicator
(3) Pro-cision Flo® Applicator(s) (included)
(Pro-cision Flo® Applicator)
Featuring Pro-cision Flo® Applicator (for easy application)
Direct to (your dog's) skin
(Easy) (simple) to use (handle) (apply)
Made in the U.S.A
Patent(s) Pending Formula

After application, the treated area may appear (wet) (or) (oily) for up to 24 hours
You may bathe your dog 48 hours after application

(Single Dose Pack) (Single Unit Pack) (Individual Unit) (Not For Sale)

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First (Dose)(Application)	_____
Second (Dose)(Application)	_____
Third (Dose)(Application)	_____
Fourth (Dose)(Application)	_____
Fifth (Dose)(Application)	_____
Sixth (Dose)(Application)	_____

To ensure continued protection of your pets, use these stickers as a reminder to apply and re-purchase (Brand name).

After treating your pet for the first time, peel off the sticker and place on your calendar that day.
Place the remaining stickers on your calendar as a reminder to apply (Brand name) monthly.

Calendar Reminder Stickers

Don't forget to re-purchase

6 months use all 6 stickers

3 months (use all 3 stickers)

[Individual stickers] Apply (Brand name)

[Individual sticker] Re-purchase (Brand name)

January 12, 2016

Use these calendar stickers as a reminder for when to reapply

- (Apply) (First) (1st) Month (Brand Name)
- (Reapply) (Second) (2nd) Month (Brand Name)
- (Reapply) (Third) (3rd) Month (Brand Name) (Time to Re-purchase)
- (Reapply) (Fourth) (4th) Month (Brand Name)
- (Reapply) (Fifth) (5th) Month (Brand Name)
- (Reapply) (Sixth) (6th) Month (Brand Name) Time to Re-purchase

Questions?

Contact your veterinarian or call our technical experts at 1-800-275-1414, (twenty four) (24) hours per day, (seven) (7) days per week.

Consult veterinarian before use



Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

(Nylar® - Registered Trademark of McLaughlin Gormley King Company)

EPA Reg. No. 2596-178
EPA Est. No. 2596-OH-1



January 12, 2016

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Kable Bo Davis PM-3

"Notification to add optional marketing statements per PR Notice 98-10" for Hartz Ref 143, EPA Reg. No. 2596-178.

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 is filing this Notification to add optional marketing statements per PR Notice 98-10.

"This notice is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Included with this application are:

- Completed application form 8570-1;
- 3 copies of the Master Label. Additions are highlighted.

If you have any additional questions or need any information, please feel free to contact me at 201-271-4800, ext. 2269 email me at lhemsarth@hartz.com

Sincerely,

A handwritten signature in black ink, appearing to read "W. Lance H. Hemsarth".

W. Lance H. Hemsarth
Senior Director, Research & Development

Encl.



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-178	2. EPA Product Manager Kable Bo David	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Reference #143	PM# 3	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

PRIA Submission R315; New product registration application. Previously filed under File symbol 2596-RTL. MRIDs from data filed with that action cited herein.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. Varies	No. per container see label	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container see label		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product Printed		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other on doses _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name W. Lance H. Hemsarh	Title Senior Director R&D	Telephone No. (Include Area Code) 201-271-4800, ext 2269
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		C. Date Application Received (Stamped)
2. Signature 	3. Title Senior Director R&D	
4. Typed Name W. Lance H. Hemsarh	5. Date 1-12-16	

PROCESSING REQUEST

Reg # 2596-176

Decision # 510976

Description: Revise Basic & Alt #1 CSF

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 11-3-2015

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Angela Hollis

Division: RD

Phone: 347-0216

Date: 1-16-2016

PROCESSING REQUEST

Reg # 2596-178

Decision # 511934

Description: additional marketing & Net Contents
verbiage

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☒ Dated: 12-31-2015

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Angela Hollis

Division: RD

Phone: 347-0216

Date: 1-4-2016



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 20, 2016

Anna McGrath
Regulatory Affairs Specialist
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, New Jersey 07094

Subject: CSF Notification per PRN 98-10 – Revised Basic & Alt 1 CSFs
Product Name: Hartz Reference #143
EPA Registration Number: 2596-178
Application Date: November 3, 2015
Decision Number: 510976

Dear Ms. McGrath:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated November 3, 2015
- Alternate CSF 1 dated November 3, 2015

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed within a large, loopy oval shape.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-178	2. EPA Product Manager Kable Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Reference #: 143	PM# 3	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, New Jersey 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION JAN 20 2016
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

"Notification for a Minor Formulation Amendment to add additional source of inert ingredient per PR Notice 98-10."

"This notice is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Anna McGrath		Title Regulatory Affairs Specialist		Telephone No. (Include Area Code) 201-271-4800 ext. 7015	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Affairs Specialist			
4. Typed Name Anna McGrath		5. Date November 3, 2015			



November 3, 2015

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Kable Bo Davis, PM-3

"Notification for a Minor Formulation Amendment to add additional source(s) of approved inert ingredient(s) per PR Notice 98-10" for Hartz Ref # 143 EPA Reg. No. 2596-178.

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 is filing this Notification for a Minor Formulation Amendment to add additional source(s) of an approved inert ingredient(s) per PR Notice 98-10.

"This notice is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Included with this application are:

- Completed application form 8570-1;
- Two copies of new Basic Confidential Statement of Formula, dated 11/3/15
- Two copies of new Alternate Confidential Statement of Formula #1, dated 11/3/15
- Copies of prior approved Basic Confidential Statement of Formula and Alternate Confidential Statement of Formula, dated 4/29/14

If you have any additional questions or need any information, please feel free to contact me at 201-271-4800, ext. 7015 or email me at amcgrath@hartzcom

Sincerely,

A handwritten signature in black ink that reads "Anna McGrath".

Anna McGrath
Regulatory Affairs Specialist



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094	EPA File Symbol/Registration Number 2596-178
	Product Name Hartz Reference #143
	Date of Confidential Statement of Formula (EPA Form 8570-4) 11/03/2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

5-Amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-4[(1R,S)-(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile; (S)-Methoprene and; Pyriproxyfen

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
5-Amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-4[(1R,S)-(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitril (S)-Methoprene Pyriproxyfen	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
Signature 	Name and Title Lance Hemsarth, Sr. Director, R&D	Date 01/20/2016

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 1.5 hours per response, including familiarization with the form, organizing the necessary information, and completing the form. Send any comments regarding the burden estimate or any other aspect of this collection of information to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 31, 2015

Lance Hemsarh
Senior Director
Research & Development
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Subject: Notification per PRN 98-10 – Additional Marketing Claims and Net Contents
Product Name: Hartz Reference #143
EPA Registration Number: 2596-178
Application Date: 12/4/2015
Decision Number: 511934

Dear Mr. Hemsarh:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", with a large, sweeping flourish at the end.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch I
Registration Division (7505P)
Office of Pesticide Programs

December 30, 2015

Hartz® Reference # 143

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

Hartz® Pro Force™ for Dogs (&) (and Puppies)
Hartz® FieldForce Pro™ for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ for Dogs (&) (and Puppies)

Hartz® Pro Force™ Triple Action Topical Solution for Dogs (&) (and Puppies)
Hartz® FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

FieldForce Pro™ for Dogs (&) (and Puppies)
First Defense Pro™ for Dogs (&) (and Puppies)
FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
Pyriproxyfen.....	0.25%
OTHER INGREDIENTS	81.15%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS:

NOTIFICATION

2596-178

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

12/31/2015

December 30, 2015

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 to 22 lbs.	0.023 fl. oz. (0.67 ml.)(Applicator)
23 to 44 lbs.	0.045 fl. oz. (1.34 ml.)(Applicator)
45 - 88 lbs.	0.091 fl. oz. (2.68 ml.)(Applicator)
89 - 132 lbs.	0.136 fl. oz. (4.02 ml.)(Applicator)

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 to 22 lbs.	0.069 fl. oz. (2.01 ml.), Contains 3(-) (tubes, each) 0.023 fl. oz. (0.67 ml.)(Applicators)
23 to 44 lbs.	0.135 fl. oz. (4.02 ml.), Contains 3 (-) (tubes, each) 0.045 fl. oz. (1.34 ml.)(Applicators)
45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3(-) (tubes, each) 0.091 fl. oz. (2.68 ml.)(Applicators)
89 - 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 (-) (tubes, each) 0.136 fl. oz. (4.02 ml.)(Applicators)

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 to 22 lbs.	0.138 fl. oz. (4.02 ml.), Contains 6 (-) (tubes, each) 0.023 fl. oz. (0.67 ml.)(Applicators)
23 to 44 lbs.	0.27 fl. oz. (8.04 ml.), Contains 6 (-) (tubes, each) 0.045 fl. oz. (1.34 ml.)(Applicators)
45 - 88 lbs.	0.546 fl. oz. (16.08 ml.), Contains 6 (-) (tubes, each) 0.091 fl. oz. (2.68 ml.)(Applicators)
89 - 132 lbs.	0.816 fl. oz. (24.12 ml.), Contains 6 (-) (tubes, each) 0.136 fl. oz. (4.02 ml.)(Applicators)



(1.5 x 1.5 cm icon)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panel. The icon will appear in a black lined yellow box.]

DO NOT USE ON CATS

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty four (24) hours per day, seven (7) days per week.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

December 30, 2015

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER

DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS

DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT

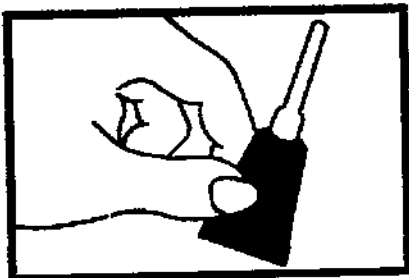
DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS

THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER

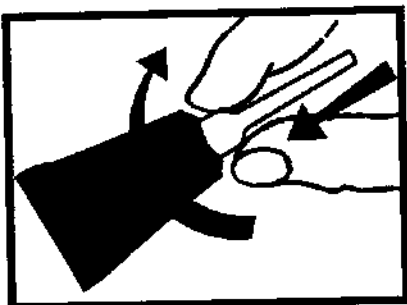


(Place in a 1.5 x 1.5 cm yellow box with black images only.)

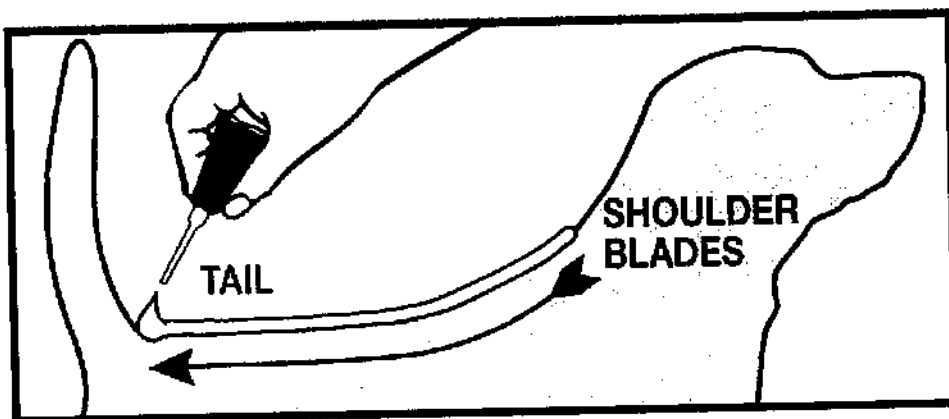
DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to or ingested by a cat, contact your veterinarian.



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



3 Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

4 Repeat every month.

SIDE EFFECTS

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to three months. PRODUCT NAME also prevents development of all flea stages for up to three months. PRODUCT NAME kills ticks for at least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to three months, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

(With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.)

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal. Do not use or store near heat or open flame.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-178
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

[Product name]

For use ONLY on DOGS AND PUPPIES 8 WEEKS OR OLDER weighing (*insert from weight range list below*) -

5 to 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 to 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains Fipronil (9.80%), (S)-Methoprene (8.80%), Pyriproxyfen (0.25%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions

EPA Reg. No. 2596-178

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

[Adult Fleas]

Kills Fleas (for (28 days) (30 days) (1 month) (4 weeks))

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills newly emerged adult fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Starts killing fleas within 30 minutes* (mins)

*48 hours after initial application

[Both statements must appear on the same panel. The qualifying statement is to be in close proximity with the same font, color and background with font size being 40% or greater.]

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)
Prevents Flea Eggs from hatching
Kills flea eggs on your (dog *or* puppy *or* dog and puppy) that live in your home
Kills flea eggs on your (dog *or* puppy *or* dog and puppy) to prevent the eggs from hatching in your home.

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older
Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older
Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older
Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)
Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all biting stages of ticks
Kills adult (brown dog) (deer) ticks, nymphs and larvae
Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations
Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice
Kills Fleas, Ticks, Flea eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, and Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, and Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.
Kills Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks and chewing lice (for dogs and puppies 8 weeks or older)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Controls flea and tick infestations
Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Prevents flea eggs from developing into biting adults in the home (for) (up to) (30 days) (1 month) (4 weeks)
Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)
Stays on and doesn't rub off
Kills fleas for 30 days (1 month) (4 weeks)
Stops and prevents infestations
Prevents re-infestation
Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) prevents re-infestation
Contains two ingredients to prevent flea infestations

Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
Waterproof
Effective after bathing
Effective after exposure to water
Easy spot on topical applicator
Patents Pending

Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Convenient to use
Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.
(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)
(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)
Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- **Fast Acting**
- **Long Lasting**
- **Waterproof**

Only for dogs and puppies 8 weeks of age or older
Specially formulated for dogs and puppies 8 weeks of age or older

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose, 4th dose, 5th dose, 6th dose

First month, second month, third month, fourth month, fifth month, sixth month

Value pack

1 month supply
3 month supply
6 month supply
1 monthly treatment

3 monthly treatment(s)
6 monthly treatment(s)
1 monthly dose
3 monthly doses
6 monthly doses
Apply monthly (every 30 days)
Convenient (easy to use) applicator
(3) Pro-cision Flo® Applicator(s) (included)
(Pro-cision Flo® Applicator)
Featuring Pro-cision Flo® Applicator (for easy application)
Direct to your dog's skin
Easy (simple) to use (handle) (apply)
Made in the U.S.A
Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours
You may bathe your dog 48 hours after application

(Single Dose Pack) (Single Unit Pack) (Individual Unit) (Not For Sale)

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose	_____
Second Dose	_____
Third Dose	_____
Fourth Dose	_____
Fifth Dose	_____
Sixth Dose	_____

To ensure continued protection of your pets, use these stickers as a reminder to apply and re-purchase (Brand name).

After treating your pet for the first time, peel off the sticker and place on your calendar that day.
Place the remaining stickers on your calendar as a reminder to apply (Brand name) monthly.

Calendar Reminder Stickers

Don't forget to re-purchase

6 months use all 6 stickers

3 months

[Individual stickers] Apply (Brand name)

[Individual sticker] Re-purchase (Brand name)

Use these calendar stickers as a reminder for when to reapply

December 30, 2015

(Apply) (First) (1st) Month (Brand Name)
(Reapply) (Second) (2nd) Month (Brand Name)
(Reapply) (Third) (3rd) Month (Brand Name) (Time to Re-purchase)
(Reapply) (Fourth) (4th) Month (Brand Name)
(Reapply) (Fifth) (5th) Month (Brand Name)
(Reapply) (Sixth) (6th) Month (Brand Name) Time to Re-purchase

Questions?

Contact your veterinarian or call our technical experts at 1-800-275-1414, twenty four (24) hours per day, seven (7) days per week.

Consult veterinarian before use



Hartz[®] and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

(Nylar[®] - Registered Trademark of McLaughlin Gormley King Company)

EPA Reg. No. 2596-178
EPA Est. No. 2596-OH-1



December 4, 2015

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Kable Bo Davis PM-3

"Notification to add optional marketing statements per PR Notice 98-10" for Hartz Ref 143, EPA Reg. No. 2596-178.

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 is filing this Notification to add optional marketing statements per PR Notice 98-10.

"This notice is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Label additions have been highlighted, including the following changes noted below that were discussed with Kable Bo Davis on 12/3/15:

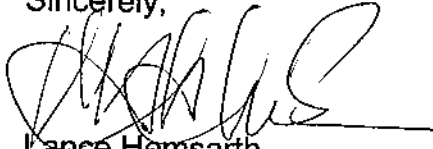
- Net Contents - the addition of a single tube package and a 6 tube package.
- Addition of Frequency of Application language. This language is the same as approved on the cat label with the only difference being the approved length of flea control (6 weeks for cats vs. 3 months for dogs).

Included with this application are:

- Completed application form 8570-1;
- 3 copies of the Master Label. Additions are highlighted.

If you have any additional questions or need any information, please feel free to contact me at 201-271-4800, ext. 2269 email me at lhemsarth@hartz.com

Sincerely,

A handwritten signature in black ink, appearing to read 'LHemsarth', written over a horizontal line.

Lance Hemsarth
Senior Director, Research & Development

Encl.



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-178	2. EPA Product Manager Kable Bo David	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Reference #143	PM# 3	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

PRIA Submission R315; New product registration application. Previously filed under File symbol 2596-RTL. MRIDs from data filed with that action cited herein.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. Varies	No. per container see label
If "Yes" Package wgt		No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container see label	
5. Location of Label Directions <input checked="" type="checkbox"/> On label		6. Manner in Which Label is Affixed to Product Printed <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other on doses	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Lance Hemsarh	Title Senior Director R&D	Telephone No. (Include Area Code) 201-271-4803, ext 2269	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Senior Director R&D	
4. Typed Name Lance Hemsarh		5. Date 12/4/15	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 30, 2015

Lance Hemsarh
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

Subject: Protocol Review – Child Resistant Packaging Test
EPA Registration Number: 2596-178
Application Date: March 20, 2015
Decision Number: 502611

Dear Mr. Hemsarh:

The protocol submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, has been reviewed. Please see the attached review dated 6/24/2015.

Please note that the Agency's review of this protocol is considered complete. Any future submissions related to this protocol must be submitted under the appropriate PRIA category.

If you have any questions, please contact Julie Chao by phone at (703) 308-8735, or via email at chao.julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed within a large, loopy oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Date: June 24, 2015

Subject: **CRP Test Protocol Review:** Sequential Child Tests and Senior Adult Use Effectiveness Tests to be conducted for Hartz Fipronil Package to determine if packaging meets the requirements of 16 CFR as required by 40 CFR 157 subpart B

Registration Number: 2596-178
DP Barcode: 426822
Decision Number: 502611
MRID(s): 49594801
Active Ingredient(s): Fipronil

From: Maggie Rudick, CRP Primary Reviewer
Bonaventure Akinlosotu, CRP Secondary Reviewer
Registration Division

Maggie Rudick

B.A.

To: Julie Chao, Risk Manager
Kable Bo Davis, Product Manager 3
Invertebrate-Vertebrate Branch 1
Registration Division (7505P)

Package Description

The registrant submitted a protocol for testing a three-unit blister package with each unit consists of a tube with a cap filled with fipronil solution.

Five separate blister package presentations will be tested each differing in the fill volume of the fipronil solution. The fill volumes tested include 0.5ml, 0.67ml, 1.34ml, 2.68ml, and 4.02ml.

Toxicity

The toxicity of the product is based only on the toxicity of Fipronil. The toxic or harmful amount of Fipronil for an 11.4 kg child is 2.5 mg/kg times 11.4 kg, which equals 28.5 mg. Access to a toxic or harmful amount = 28.5 mg divided by $[1114 \text{ mg/ml} \times 0.097 \text{ fipronil}] = 0.26 \text{ ml}$ for EPA Reg # 2596-178. The failure level for all fill volumes is access to one applicator tube.

Summary of Findings

This CRP protocol submission was reviewed by the RD CRP team and several issues need to be addressed and/or corrected in the protocol relating to the package. The Agency and the registrant need to agree or the data could be rejected upon submission. In addition to the stated pass/failure determination for the SAUE test and sequential child test, the following clarifications within the protocol must be addressed in your study:

- A unit failure for the child test should be defined as any opening, puncture, tear, breach/penetration of the unit, a visible incision or opening made by a child, or any amount of placebo/water accessed.
- A Senior Adult Use Effectiveness failure is failure to open the unit in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, cutting the unit incorrectly while opening it and/or exposure to placebo/water during prescribed test time for either the first or second package. Additionally, if the test subject is exposed to any of the pesticide while opening the package, this would constitute a failure
- If additional package opening instructions are included on the label, these must be provided to the senior test subject.
- The final report should also include the ASTM classification and opening instructions.

Conclusions

The protocol (2596-178) submitted with MRID 49594801 is accepted with comments. The submitter must ensure the issues outlined in the "Summary of Findings" are addressed in their CRP and SAUE testing.

Chao, Julie

From: Chao, Julie
Sent: Thursday, April 16, 2015 12:34 PM
To: Rudick, Maggie
Subject: CRP Package (DP426822)
Attachments: DP426822.pdf; Acute Tox Review for 2596-178.pdf; Cover Letter.pdf

Hi Maggie,

Attached is a CRP data package. The submission is a test protocol for 2596-178, although the same testing method may be applied to other Hartz fipronil formulations.

Copies of the bean sheet, submission cover letter, and acute toxicity review for 2596-178 are attached. The protocol is available in Documentum.

Please let me know if you need anything else, or if you would like a hard copy.

Thanks!

Julie

+++++

Julie Chao, MA, MSPH
Invertebrate & Vertebrate Branch 1
Registration Division
Office of Pesticide Programs
703.308-8735 (phone)

Memorandum

Date: 4 / 6 / 2015

To: 3, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 06, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 23-MAR-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 965957

Milestone: Mail

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☒ Yes ☐ No

Company: 2596 THE HARTZ MOUNTAIN CORPORATION

Billable: ☒ Yes ☐ No

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 3

Product #: 2596-178

Product Name: HARTZ REFERENCE # 143

Override:

Me Too

Me Too Product

Section 3

Name

Application Date: 20-Mar-2015

OPP Rec'd Date: 23-Mar-2015

Front End Date: 23-Mar-2015

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

AMENDMENT PROTOCOL REVIEW, CHILD RESISTANT CLOSURE.

Receipt Content

Other

CHILD RESISTANT P

View/Edit

Form A: ☐

Signature Date

Form B: ☐

Signature Date

New Ingredient

Request Date

New Ingredient

Received Date



49594800

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

March 20, 2015

FedEx

U.S. Environmental Protection Agency
Document Processing Desk (CRP Draft Test Protocol)
Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Re: Request for protocol review, Child Resistant Closure, Hartz Test #2683
PRIA Code R272, use on fipronil based product(s) and others

Dear Mr. Davis,

Please find enclosed an application requesting a review of a child resistant closure protocol, Hartz Test #2683. This test may be used on packaging for our fipronil based products. There may be other products in the future. This review should qualify for PRIA Code R272.

This application includes the following enclosed documents:

- Original cover letter
- Check Number 338385 payable to US Environmental Protection Agency for \$2409.00
- Transmittal Document
- Application Form (EPA Form 8570-1, 3 copies)
- No Claim of Data Confidentiality statements (3 copies)
- Three (3) copies of the Hartz Test #2683

Please feel free to contact me directly if there are questions or concerns about this submission.

Sincerely,

David Jones
Manager Regulatory Affairs
djones@hartz.com
Direct extension – 7414

Encl.

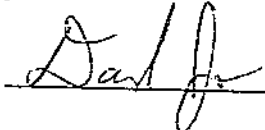
cc: S. McNear, L. Hemsarth

TRANSMITTAL DOCUMENT

Submitter:

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Company Contact:



Typed Name of Contact: David Jones

Phone: (201) 271-4800, ext. 7414

Fax: (201) 271-0357

E-mail: djones@hartz.com

Regulatory Action in Support of Which This Package is Submitted:

HARTZ Test #2683, Child Resistant Closure Test Protocol proposed by The Hartz Mountain Corporation, Company Number 2596

Submission Date:

03/20/2015

List of Submitted Documents:

Cover letter

Check No. 338385 for \$2409.00

Transmittal Document

Application Form (3 copies)

No Claim of Data Confidentiality Statement

49594801 Hartz Test #2683 (3 copies)

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 4/13-15

Document Part Of: 2596-178
MRID, If Any: 495948

Content Screen: Recommended to
Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

SHAUNTA HILL

PRIA 3 – 21 Day Content Screen Review Worksheet
(EPA/OPP Use Only)

21 Day Screen Start Date: 3-23-15 September 2012

Experts In-Processing Signature: B.B. Date 3-25-15 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>2596-178</u>		EPA Receipt Date: <u>3-23-15</u>			
Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type		<input checked="" type="checkbox"/>		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)				<input checked="" type="checkbox"/>
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	yes <input type="checkbox"/> no <input type="checkbox"/>			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)				<input checked="" type="checkbox"/>
	Certificate and data matrix consistent				
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes <input type="checkbox"/> no <input type="checkbox"/>			
	If applicable, is there a letter of Authorization for exclusive use only.				
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)				<input checked="" type="checkbox"/>
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)				<input checked="" type="checkbox"/>
5	a) Selective Method (Fee category experts use)	yes <input type="checkbox"/> no <input type="checkbox"/>			
	b) Cite-All (Fee category experts use)				
	c) Applicant owns all data (Fee category experts use)				
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)				<input checked="" type="checkbox"/>
7	Is the data package consistent with PR Notice 86-5		<input checked="" type="checkbox"/>		
8	Notice of Filing included with petitions				<input checked="" type="checkbox"/>

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Documentation : Pass

Required forms are complete

Inerts: N/A

II-3 : Pass

MRID 495948

Status : Pass

KC 4/8/2015

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 24, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-502611
EPA File Symbol or Registration Number: 2596-178
Product Name: HARTZ REFERENCE # 143
EPA Receipt Date: 23-Mar-2015
EPA Company Number: 2596
Company Name: THE HARTZ MOUNTAIN CORPORATION

DAVID JONES
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment (protocol review) and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R272

APPLICANT-INITIATED 2;EXCLUDES DART, PRE-REGISTRATION CONFERENCES,
RAPID RESPONSE REVIEW, DNT PROTOCOL REVIEW, PROTOCOLS NEEDING HSRB
REVIEW;REVIEW OF STUDY PROTOCOL;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-8961.

Sincerely,

A handwritten signature in black ink, appearing to be "m. jones".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{965957 ~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 3

Receipt No.

S- 965957

EPA File Symbol/Reg. No.

2596-178

Pin-Punch Date:

3/23/2015

This item is NOT subject to FFS action.

Action Code:

Requested: R272

Granted: R272

Amount Due: \$ 2,409

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Jennifer Gaines

Date: 3/31/15

Remarks:



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-178	2. EPA Product Manager K. Davis	3. Proposed Classification <input type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Test #2683 (proposed test protocol)	PM# 3	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation, 400 Plaza Dr. Secaucus, NJ 07094 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Child Resistant Packaging Test Protocol from The Hartz Mountain Corporation proposed to verify packaging as CRP.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David Jones	Title Mgr. Regulatory Affairs	Telephone No. (Include Area Code) (201) 271-4800
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamper!)
2. Signature 	3. Title Manager Regulatory Affairs	
4. Typed Name David Jones	5. Date March 20, 2015	

Receipt for Section 3

S: 965957

Milestone: All:

Regulatory Type: Product Registration - Section 3



Resubmission: ☐ Yes ☒ No

Application Type: Amendment



Fee For Service: ☐ Yes ☒ No

Billable: ☐ Yes ☒ No

Company: 2596 THE HARTZ MOUNTAIN CORPORATION



Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 3



Product #: 2596-178

Product Name: HARTZ REFERENCE # 143

Override#:

Me Too

Section3:

Me Too Product

Name:

Application Date: 20-Mar-2015



OPP Rec'd Date: 23-Mar-2015



Front End Date: 23-Mar-2015



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

AMENDMENT PROTOCOL REVIEW;CHILD RESISTANT CLOSURE.

Receipt Content

Other

De

CHILD RESISTANT P

View/Edit

Form #: ☐

Signature Date:

Form #: ☐

Signature Date:



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

March 20, 2015

FedEx

U.S. Environmental Protection Agency
Document Processing Desk (CRP Draft Test Protocol)
Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Re: Request for protocol review, Child Resistant Closure, Hartz Test #2683
PRIA Code R272, use on fipronil based product(s) and others

Dear Mr. Davis,

Please find enclosed an application requesting a review of a child resistant closure protocol, Hartz Test #2683. This test may be used on packaging for our fipronil based products. There may be other products in the future. This review should qualify for PRIA Code R272.

This application includes the following enclosed documents:

- Original cover letter
- Check Number 338385 payable to US Environmental Protection Agency for \$2409.00
- Transmittal Document
- Application Form (EPA Form 8570-1, 3 copies)
- No Claim of Data Confidentiality statements (3 copies)
- Three (3) copies of the Hartz Test #2683

Please feel free to contact me directly if there are questions or concerns about this submission.

Sincerely,

A handwritten signature in black ink, appearing to read "David Jones".

David Jones
Manager Regulatory Affairs
djones@hartz.com
Direct extension ~ 7414

Encl.

cc: S. McNear, L. Hemsarth

Hartz®

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

CORPORATION

No.

338385

DATE: 11-MAR-15

VENDOR NAME:

US ENVIRONMENTAL PROTECTION AGENCY

VENDOR NO: 1992

INVOICE NO	INVOICE DATE	DESCRIPTION	DISCOUNT AMOUNT	NET AMOUNT
PRIA FEE	05-MAR-15	1000109874	0.00	2,409.00

PLEASE DETACH AND RETAIN THIS STATEMENT AS YOUR RECORD OF PAYMENT.

Thank You!

0.00

2,409.00

THIS CHECK IS PROTECTED BY A VOID PANTOGRAPH, MICROPRINT SIGNATURE LINE AND A HEAT SENSITIVE PADLOCK ICON. ADDITIONAL SECURITY FEATURES ARE LISTED ON BACK.

Hartz®

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS NJ, 07094

Bank of America

64-1278
611 GA

No. **338385**

CHECK DATE
11-MAR-15

CHECK NUMBER
338385

CHECK AMOUNT
****2,409.00

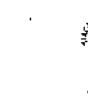
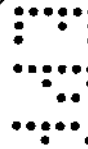
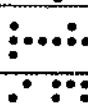
PAY Two Thousand Four Hundred Nine Dollars And 00 Cents*****

TO
THE
ORDER
OF

US ENVIRONMENTAL PROTECTION AGENCY
PESTICIDE REGISTRATION SERVICE FEE
PO BOX 979031
ST LOUIS, MO 63197-9000

By

By

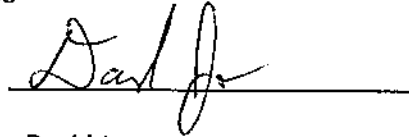


TRANSMITTAL DOCUMENT

Submitter:

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Company Contact:



Typed Name of Contact: David Jones

Phone: (201) 271-4800, ext. 7414

Fax: (201) 271-0357

E-mail: djones@hartz.com

Regulatory Action in Support of Which This Package is Submitted:

HARTZ Test #2683, Child Resistant Closure Test Protocol proposed by The Hartz Mountain Corporation, Company Number 2596

Submission Date:

03/20/2015

List of Submitted Documents:

Cover letter

Check No. 338385 for \$2409.00

Transmittal Document

Application Form (3 copies)

No Claim of Data Confidentiality Statement

Hartz Test #2683 (3 copies)

